VII. SAFETY AND EFFECTIVENESS SUMMARY

The STA®-Calibrator HBPM/LMWH kit is intended for use as a set of plasma standards for the calibration of assays of low molecular weight heparins (LMWH) by STA® analyzers (K942117) by the anti-Xa method.

These LMWH calibrators are assayed against a secondary standard of the 85/600 International Standard for LMWH established in 1987.

Each kit provides 3 sets of calibrator levels ([0], [9] and [18]), each set consisting of 4 x 1-ml vials of freeze-dried normal human citrated plasmas that have been supplemented with different quantities of LMWH, their accurately assay values being indicated in 3 assay value inserts supplied with the kit for each manufactured lot.

The freeze-dried calibrators are stable for 24 months from the date of manufacture, when stored at 2°-8°C. After reconstitution, the calibrators are stable for 4 hours on board STA® analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 9 2001

Andrew Loc B. Le, Ph.D.
Director for Regulatory Affairs and Quality Assurance
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Re: K010350
Trade Name: Diagnostica Stago STA®-Calibrator HBPM/LMWH Kit
Regulation Number: 21 CFR 864.5425
Regulatory Class: II
Product Code: GGN
Dated: February 2, 2001
Received: February 2, 2001

Dear Dr. Le:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment A

510(k) Number : K010350

Device Name: STA®-Calibrator HBPM/LMWH Kit

Indications for Use:

The STA®-Calibrator HBPM*/LMWH kit provides a set of three plasma standards intended for the calibration of low molecular weight heparin (LMWH) assays performed on the fully automatic STA® analyzers (K942117) by the anti-Xa colorimetric method.

(*) HBPM is the French name of low molecular weight heparin (Héparines de Bas Poids Moléculaire)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Joseph I. Hackett

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)